REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 2, 17-19, 21, 23-28, 31, 32, 43-60, 62, 63, 82-90 and 94-107 are under examination in this application. Claims 1, 2, 21, 31, 32, 50, 51, 60, 62, 63, and 82-90 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Claims 61, 64, and 91-93 are cancelled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Claims 94-107 are added to round out the scope of protection to which Applicants are entitled.

No new matter has been added by these amendments. Support for the amended claims can be found throughout the specification. Particularly, support for reduction of the symptoms of PCV-2 by eliciting an immune response can be found on page 31, lines 1-7. Support for the recitation "in a population of pigs" can be found on page 28, lines 2-3. Support for minimizing the symptoms of PCV-2 can be found on page 30, lines 1-7. More specifically, the exclusion of other agents as the cause of symptoms associated with PCV-2 is indicative that PCV-2 is the cause of such symptoms and that administration of a composition that elicits an immune response against PCV-2 will minimize those symptoms. Support for the recitation of a PCV-2 polypeptide can be found of page 6, line 11 and on page 25, line 19 of the application. Support for the recitation of a PCV-2 antigen can be found on page 23, lines 5-7 of the application.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support is found throughout the specification and from the pending claims.

II. THE OBJECTIONS ARE OVERCOME

The specification was objected to based on a typographical error in the table on page 39. The Abstract was further objected to because the Abstract of the Disclosure exceeded to allowable length. Several claims were objected to based on a typographical error and improper dependence. These issues were corrected by the Amendment and Response to Office Action with Requests for Extension of Time and Interview, filed via Express Mail on March 4, 2002. It is requested that the objections to the specification and claims be withdrawn since the appropriate corrections have been made.

III. THE DOUBLE PATENTING REJECTION IS OVERCOME

Claims 4-6, 8, 34-38, 42 and 65-81 of this application allegedly conflict with claims 4-6, 8, 34-38, 42 and 65-81 of U.S. application Serial No. 09/583,350. Claims 1-3, 9-11, 17-29, 31-33, 37, 39-41, and 43-64 were provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly unpatentable over claims 87, 90-97, 100, and 102-109 of copending U.S. application Serial No. 09/161,092. These issues were addressed in the March 4, 2002 Amendment and Response. Accordingly, reconsideration and withdrawal of the double patenting rejection, or at least holding it in abeyance until agreement is reached as to allowable subject matter, is respectfully requested.

IV. THE REJECTIONS UNDER 35 U.S.C. § 112, 2ND PARAGRAPH, ARE OVERCOME

The rejections under 35 U.S.C. §112, second paragraph, were addressed in the March 4, 2002 Amendment and Response, wherein reconsideration and withdrawal of the rejections were respectfully requested.

V. THE REJECTIONS UNDER 35 U.S.C. § 112, 1ST PARAGRAPH, ARE OVERCOME

The Application Provides an Adequate Written Description

Claims 1-3, 7, 9-11, 17-29, 31-33, 37, 39-41 and 43-64 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time of filing. The Applicants respectfully disagree. It is submitted that the present application provides an adequate written description of the claimed invention; thus, the following traverse is offered.

The Office Action alleges that the specification fails to define "pathologic sequelae" and how it is associated with PCV-2. The claims that referred to pathologic sequelae associated with PCV-2 were rewritten in the March 4, 2002 Amendment and Response so that they no longer recite the phrase "pathologic sequelae"; thus the rejection on this basis is moot.

The Office Action further contends that the specification allegedly fails to "define every possible immunogen capable of eliciting a humoral and/or cell-mediated immune response to PCV-2". The claims have been amended such that they no longer recite "a PCV-2 immunogen". Instead, the independent claims are drawn to a polypeptide, an antigen, or an epitope, that is specific to PCV-2.

In contrast to the statements made in the Office Action regarding these points, the results of Example 10 are consistent with there being an immune response elicited in swine hosts following the administration of vectors expressing open reading frames 13 (ORF 13) and/or 4 (ORF4). In the example, it was shown that piglets to which recombinant plasmids expressing ORF13 and/or ORF4 were administered, showed a significantly reduced level of viral load in bronchial and mesenteric lymph node tissue following PCV-2 challenge.

Furthermore, the Declaration of Dr. Catherine Charreyre from USSN 09/884,514 (Charreyre Declaration), submitted with the Amendment mailed on March 4, 2002, describes the results of a piglet vaccination study using inactivated PCV-2, wherein a subgroup of piglets was administered inactivated PCV-2 and then later challenged with live PCV-2 in order to determine if a protective immune response had been achieved with the inactivated PCV-2. The results show that the piglets seroconverted after a second administration of the inactivated virus. Further, a reduction of PCV-2 excretion in feces was observed in the piglets that received the inactivated virus. The data also indicated a decrease in detectable levels of PCV-2 in mediastinal or mesenteric lymph nodes of piglets following challenge by PCV-2 virus. Lastly, there was a significant reduction of lesions in piglets having previously been administered inactivated PCV-2 that were later challenged with PCV-2 virus over those piglets that were not administered inactivated PCV-2.

Example 10 and the Charreyre Declaration are sufficient to demonstrate that there in fact is an immune response generated from the administration of PCV-2 immunogen compositions, including, but not limited to, inactivated virus and vectors expressing PCV-2 immunogen DNA sequences. To reflect this data, independent claims 1 and 31 have been amended, and are now

drawn to a composition for eliciting an immune response, thereby reducing the symptoms of PCV-2 infection. Thus, Applicants clearly had possession of the claimed invention, and the written description rejection under 35 U.S.C § 112, first paragraph, is overcome.

The Application Provides an Enabling Disclosure

Claims 1-3, 7, 9-11, 17-29, 31-33, 37, 39-41 and 43-64 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable on skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully disagrees.

It is argued in the Office Action that Applicants were not in possession of all immunogens to PCV-2 due to the lack of guidance provided by the inventors as to the possible common structure of every possible PCV-2 immunogen capable of eliciting the desired immune response. As stated above and in the March 4, 2002 Amendment and Response, the claims were amended to remove reference to "pathologic sequelae" and to more clearly define the immunogens claimed. Therefore, the claims are not, as the Office Action alleges at page 11, "drawn to treating any disease or syndrome associated with PCV-2...with any immunogen to PCV-2." Rather, they are directed to the symptoms of myocarditis, abortion and/or intrauterine infection, wherein live attenuated PCV-2, inactivated PCV-2 or PCV-2 subunits are the immunogen.

It is further argued in the Office Action that there is insufficient data in the examples to demonstrate that PCV-2 elicits the desired immune response. Applicants respectfully disagree. Example 11, in particular, demonstrates a significant reduction of lymph node lesions in piglets vaccinated with either a plasmid comprising ORF 13 or a plasmid comprising ORF 4 and ORF 13, indicating an immune response in vaccinated piglets. In addition to the examples presented in the application, the previously submitted Charreyre Declaration, unequivocally demonstrates that PCV-2 elicits the desired immune response in piglets. A significantly higher antibody titer was observed in piglets vaccinated with inactivated PCV-2 following a challenge with PCV-2, compared with a control group. Differences in necropsy lesions and viral load in lymph node tissue were also significant between vaccinated and control groups.

Further still, the Examiner is invited to review the myriad of documents cited in the present application, e.g., at pages 18-19, 19-20, 20 and 22-23, *inter alia*. Also, with respect to using viral or DNA plasmid vectors, data demonstrating reduction in viral load, duration of post

challenge hyperthermia and duration of viral excretion in pigs vaccinated with a DNA plasmid containing ORF 2 or ORF 1 and 2 of PCV-2 can be found in Example 10 of U.S.S.N. 09/586,535, currently under examination by Examiner Li. Likewise, Example 9.3 of U.S.S.N. 09/583,545, contains data showing a significant reduction in lymph node lesions following immunization with a vector comprising ORF 2 or ORF 2 and ORF 1 in a canarypox vector. Finally, this Examiner has allowed claims to immunogenic compositions that comprise DNA plasmid or viral vectors in the cases of U.S.S.N. 09/161,092 and U.S.P.N. 6,368,601. For example, claim 22 of U.S. Patent No. 6,368,601 is to an immunogenic composition comprising a canarypox viral vector and an isolated DNA molecule comprising, *inter alia*, ORF 4 or ORF 13. Claim 23 similarly involves an immunogenic composition comprising a DNA plasmid vector and, *inter alia*, ORF 4 or ORF 13.

According to the Court of Appeals for the Federal Circuit in the case of *In re Wands*, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988),

> Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is undue, not experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ... [Citations omitted].

Id. at 1404.

Against this background, determining whether undue experimentation is required to practice a claimed invention turns on weighing many factors summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). For example, (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

The assertion in the Office Action that the instant invention does not provide enablement for a method and composition for preventing myocarditis, abortion and intrauterine infection

associated with porcine circovirus-2 is misplaced because undue experimentation would not exist. Applying *Wands* to the instant facts, it is clear that enablement exists: the quantity of experimentation necessary is low; the amount of direction or guidance presented is high; working examples are clearly present; the relative skill of those in the art is high; and the predictability of the art is also high.

It is respectfully submitted that adequate guidance is provided to enable the skilled artisan to practice the claimed invention without undue experimentation. Therefore, reconsideration and withdrawal of the U.S.C. § 112, first paragraph rejections are earnestly solicited.

CONCLUSION

No fee is believed to be due for consideration and entry of this paper, however, the Commissioner is hereby authorized to charge any fee occasioned by this paper to Deposit Account No. 50-0320.

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

1. (Twice amended) A[n immunological or immunogenic] composition for eliciting an immune response and thereby reducing[the prevention and/or treatment of] porcine circovirus-2 (PCV-2)-caused myocarditis, and/or abortion and/or intrauterine infection in a population of pigs comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector containing and expressing an exogenous nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 polypeptide[for a PCV-2 immunogen].

2. (Twice amended) A[n immunological or immunogenic] composition for eliciting an immune response and thereby reducing[the prevention and/or treatment of] PCV-2-caused myocarditis and/or abortion and/or intrauterine infection associated with PCV-2 comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector containing and expressing an exogenous nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 antigen[for a PCV-2 immunogen].

21. (Twice amended) The composition of claims 1 or 2, additionally including at least one immunogen from at least one additional pig pathogen, or a vector expressing such an immunogen, wherein the vector, the at least one immunogen from at least one additional pig pathogen can also be the vector expressing the PCV-2 polypeptide or antigen[immunogen].

31. (Twice amended) A method for minimizing the symptoms[the prevention and/or treatment] of porcine circovirus-2 (PCV-2)-caused myocarditis, and/or abortion and/or intrauterine infection in a population of pigs comprising inducing an immunological or immunogenic response against PCV-2 in the population of pigs[a pig] comprising administering to the population of pigs[pig] the composition of claim 1.

32. (Twice amended) A method for minimizing the symptoms[the prevention and/or treatment] of PCV-2-caused myocarditis and/or abortion and/or intrauterine infection in a population of pigs comprising inducing an immunological or immunogenic response against PCV-2 in the population of pigs[a pig] comprising administering to the population of pigs[pig] the composition of claim 2.

50. (Twice amended) The method of claim 31, additionally including at least one immunogen from at least one additional pig pathogen, or a vector expressing such an

immunogen, wherein the vector, the at least one immunogen from at least one additional pig pathogen, can also be the vector expressing the PCV-2 polypeptide[immunogen].

51. (Twice amended) The method of claim 32, additionally including at least one immunogen from at least one additional pig pathogen, or a vector expressing such an immunogen, wherein the vector, the at least one immunogen from at least one additional pig pathogen, can also be the vector expressing the PCV-2 antigen[immunogen].

60. (Twice amended) The method of claims 31 or 32, wherein the polypeptide or antigen[immunogen] is recombinantly produced.

62. (Amended) The method of claims 31 or 32,[61] wherein the administering is prior to breeding.

63. (Amended) The method of claims 31 or 32,[61] wherein the population includes one or more pregnant female pigs and the administering is during pregnancy of the one or more female pigs.

82. (Amended) A[n immunological or immunogenic] composition for eliciting an immune response and thereby reducing[the prevention and/or treatment of] porcine circovirus-2 (PCV-2)-caused myocarditis comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector containing and expressing an exogenous nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 polypeptide[for a PCV-2 immunogen].

83. (Amended) A[n immunological or immunogenic] composition for eliciting an immune response and thereby reducing[the prevention and/or treatment of] porcine circovirus-2 (PCV-2)-caused abortion comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector containing and expressing an exogenous nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 polypeptide[for a PCV-2 immunogen].

84. (Amended) A[n immunological or immunogenic] composition for eliciting an immune response and thereby reducing[the prevention and/or treatment of] porcine circovirus-2 (PCV-2)-caused intrauterine infection comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector containing and expressing an exogenous nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 polypeptide[for a PCV-2 immunogen].

85. (Amended) A[n immunological or immunogenic] composition for eliciting an immune response and thereby reducing[the prevention and/or treatment of] porcine circovirus-2 (PCV-2)-caused myocarditis comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector containing and expressing an exogenous nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 antigen[for a PCV-2 immunogen].

86. (Amended) A[n immunological or immunogenic] composition for eliciting an immune response and thereby reducing[the prevention and/or treatment of] porcine circovirus-2 (PCV-2)-caused abortion comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector expressing and containing and expressing nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 antigen[for a PCV-2 immunogen].

87. (Amended) A[n immunological or immunogenic] composition for eliciting an immune response and thereby reducing[the prevention and/or treatment of] porcine circovirus-2 (PCV-2)-caused intrauterine infection comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector containing and expressing an exogenous nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 antigen[for a PCV-2 immunogen].

88. (Amended) A method for eliciting an immune response and thereby reducing[the prevention and/or treatment of] porcine circovirus-2 (PCV-2)-caused myocarditis comprising inducing an immunological or immunogenic response against PCV-2 in a pig comprising administering to the pig the composition of claim 1, 2 or 94.

89. (Amended) A method for eliciting an immune response and thereby reducing[the prevention and/or treatment of] porcine circovirus-2 (PCV-2)-caused abortion comprising inducing an immunological or immunogenic response against PCV-2 in a pig comprising administering to the pig the composition of claim 1, 2 or 94.

90. (Amended) A method for eliciting an immune response and thereby reducing[the prevention and/or treatment of] porcine circovirus-2 (PCV-2)-caused intrauterine infection comprising inducing an immunological or immunogenic response against PCV-2 in a pig comprising administering to the pig the composition of claim 1, 2 or 94.